In the United States Court of Federal Claims

No. 19-111
(Filed: 7 August 2024*)

DUANE HOFFMAN,	*
	*
Petitioner,	*
	*
v.	*
	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
	*
Respondent.	*
	*

Isiah Kalinowski, Bosson Legal Group, of Fairfax, VA, for petitioner.

Felicia Langel, Trial Attorney, Civil Division, Department of Justice, of Washington, DC, for respondent.

OPINION AND ORDER

HOLTE, **Judge.**

"'[W]hile most of the Nation[] . . . enjoy[s] great[] benefit from immunization programs, a small but significant number have been gravely injured.'" *Cloer v. Sec'y of Health & Hum Servs.*, 654 F.3d 1322, 1325 (Fed. Cir. 2011) (quoting H.R. Rep. No. 99-908 at 4 (1986)). "'[F]or the relatively few who are injured by vaccines,'" Congress determined the "'opportunities for redress and restitution [were] limited, time-consuming, [and] expensive.'" *Id.* Congress thus "created the Vaccine Program" to "compensate injured persons quickly and fairly" for injuries "either presumed or proven to be causally connected to vaccines." *Id.*

Petitioner Duane Hoffman moved for review of Special Master Moran's decision holding petitioner is not entitled to compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1–300aa-34 ("Vaccine Act"). Mr. Hoffman, who suffers from chronic lymphocytic leukemia and chronic obstructive pulmonary disease, received the influenza ("flu") vaccine on 7 January 2017. Seventeen days later, Mr. Hoffman experienced low back pain and bilateral lower extremity pain, weakness, and numbness. Mr. Hoffman was diagnosed

* This opinion was initially filed under seal on 8 July 2024 pursuant to Vaccine Rule 18(b) of the Rules of the Court of Federal Claims. The Court provided the parties 14 days to submit proposed redactions, if any, before the opinion was released for publication. Neither party proposed redactions. This opinion is now reissued for publication in its original form.

with Guillain-Barré syndrome shortly thereafter. On 9 October 2017, after months of unsuccessful treatment, Mr. Hoffman's diagnosis was changed to chronic immune demyelinating polyradiculopathy ("CIDP"). Mr. Hoffman alleges his CIDP was caused by the flu vaccine. On 10 January 2024, Special Master Moran denied Mr. Hoffman's petition for compensation. In doing so, the Special Master concluded "Mr. Hoffman has failed to meet his burden of proof regarding *Althen* prong one" because "Mr. Hoffman based part of his claim on a level of proof (plausibility) that is lower than the required level of proof, which is preponderant evidence." Corrected Decision Deny. Compensation ("SM Dec.") at 2, 21, ECF No. 90.[1]

Pursuant to the Vaccine Act, a petitioner must show "by a preponderance of the evidence," 42 U.S.C. § 300aa-13(a)(1)(A), he "sustained . . . [the relevant] illness, disability, injury, or condition not set forth in the Vaccine Injury Table . . . which was *caused by* [the] vaccine." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(II) (emphasis added). As interpreted by the Federal Circuit, and as relevant here, the Vaccine Act therefore requires petitioners to "show by preponderant evidence that the vaccination brought about [their] injury by providing: (1) a medical theory causally connecting the vaccination and the injury. . . ." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010). The Federal Circuit has clarified, however, petitioners can "me[e]t th[is] first . . . prong[] of the *Althen* test" by presenting "a 'biologically plausible' theory." *See Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Hum. Servs.,* 569 F.3d 1367, 1375 (Fed. Cir. 2009). Thus, by requiring Mr. Hoffman to present "persuasive evidence" of a "persuasive theory," *see* SM Dec. at 8–9, the Special Master "impermissibly rais[ed] . . . [Mr. Hoffman's] burden under the Vaccine Act." *Andreu*, 569 F.3d at 1378. For this reason, and as further explained below, the Court grants petitioner's Motion for Review, vacates the Special Master's decision, and remands this case for further proceedings consistent with this Opinion and Order.

I. Petitioner's Medical History and Flu Vaccination

The Court's recitation of the background facts draws from the Special Master's Corrected Public Decision Denying Compensation, SM Dec. at 2 n.2 ("[T]he parties agree that the medical

[1] The concept of a "preponderance of the evidence," also called "persuasive evidence" by the Special Master and respondent in this case, is well understood. *See* SM Dec. at 8. As explained by the Federal Circuit more than thirty years ago, "the 'preponderance of the evidence' standard refer[s] to[,] in the Vaccine Act[,] . . . proof by a simple preponderance, of 'more probable than not' causation." *See Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen v. Sec'y of Health & Hum Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); then citing (citing *Hellebrand v. Sec'y of Health & Human Servs*., 999 F.2d 1565, 1572–73 (Fed.Cir.1993)); Tr. at 30:7–10 ("[PETITIONER:] I want to differentiate the scale of preponderant evidence [which is] 50 percent [and] a feather, which is . . . a perfect description [since it] is an enumerative quantitative scale [from plausibility.]"); Tr. at 22:7–8 ("[RESPONDENT:] We typically refer to [preponderance of the evidence] as 51 percent."); *see also Preponderance of the Evidence*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("[t]he greater weight of the evidence"). Preponderance of the evidence is, as explained by Justice Thomas, an "evidentiary standard" of proof. *See Concrete Pipe & Prods of California, Inc. v. Constr. Laborers Pension Trust for S. California*, 508 U.S. 602, 651 n.* (1993) (Thomas, J., concurring). Plausibility, on the other hand, is less a quantitative probability standard and more a qualitative inquiry into whether a fact is "[c]onceivably true," *see Plausible*, BLACK'S LAW DICTIONARY (11th ed. 2019), or credible. *See Plausible*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (3rd ed. 2021) ("4a: superficially worthy of belief: credible"); *see also* Tr. at 30:10–20 ("[PETITIONER:] [T]he Federal Circuit decisions . . . talk[] about a scale that's different [than the quantitative preponderance scale], and that's weighing the theory, and it goes between possible . . . and medical certainty.").

records accurately describe what happened to Mr. Hoffman close in time to when the medical record was created. Thus, there are no disputes about what transpired in Mr. Hoffman's case."), and the parties' briefing before the Court. *See* Mot. for Review and Mem., ECF Nos. 91, 91-1; Resp't's Resp. at 1, ECF No. 93 ("Respondent adopts and incorporates the facts and procedural history as set forth in th[e Special Master's] Decision which, to respondent's understanding, are accurate and not in dispute.").

In March 2015, petitioner Duane Hoffman was diagnosed with chronic lymphocytic leukemia (CLL). *See* Pet'r's Medical Records from Ohio Hematology Oncology ("OH Oncology"), Pet'r's Ex. 8 at 3, ECF No. 7-9. He also suffers from chronic obstructive pulmonary disease (COPD). *See* Pet'r's Medical Records from Marion General Hospital ("Marion General Records"), Pet'r's Ex. 4 at 651, ECF No. 7-5. In January 2017, Mr. Hoffman was hospitalized due to "an exacerbation of" his COPD. SM Dec. at 2; *see* Marion General Records at 657; *see also* Mot. for Review at 1. On 7 January 2017, while hospitalized, Mr. Hoffman received an influenza vaccine. *See* Vaccination Record from Marion General Hospital ("Vaccination Record"), Pet'r's Ex. 1 at 1, ECF No. 7-2. Approximately twenty days later, Mr. Hoffman "presented with bilateral lower extremity pain, weakness, and numbness." Mot. for Review at 1 (citing Marion General at 825–27); *see* Pet'r's Medical Records from Riverside Methodist Hospital ("Riverside Methodist Records"), Pet'r's Ex. 7 at 25, ECF No. 7-8; *see also* SM Dec. at 2 ("Mr. Hoffman was diagnosed with low back pain on January 24, 2017."). At that time, he "went to the emergency room at Marion General Hospital" and was subsequently "transferred to Riverside Methodist Hospital [("Riverside")] where his records indicate that his lower back pain began four days" earlier. Resp't's Rep. at 2, ECF No. 25; *see* Riverside Methodist Records at 53. Following continued pain, Mr. Hoffman underwent additional examination and diagnostic testing first at Marion General Hospital and then again at Riverside and was subsequently diagnosed "with a neurologic disorder, Guillain-Barré syndrome [(GBS)]." SM Dec. at 2 (citing Riverside Methodist Records at 261, 876–81).

Mr. Hoffman was treated for GBS using a "standard" course of intravenous immunoglobulin (IVIG). SM Dec. at 4. During this treatment, "at least one doctor stated that the flu vaccine caused Mr. Hoffman's GBS." *Id.* (citing Riverside Methodist Records at 266). "[E]ight months after [his] diagnosis of GBS, Mr. Hoffman saw Dr. Eubank," a neurologist he had seen earlier in his treatment. *Id.* (citing *see* Pet'r's Updated Medical Records from OhioHealth Neurological Physicians ("Neurological Update"), Pet'r's Ex. 19 at 66, ECF No. 18-3). On 9 October 2017, during a follow-up with Dr. Eubank, Mr. Hoffman's diagnosis was changed to chronic immune demyelinating polyradiculopathy ("CIDP"). *Id.* (citing Neurological Update at 66). Dr. Eubank explained he "previously thought that [Mr. Hoffman] had [GBS] but [because] . . . [Mr. Hoffman] continued to have some worsening . . . and subsequently improved with a course of IVIG for 5 days,[th]is would not be typical for" GBS. *Id.* (quoting Neurological Update at 66). A second neurologist, Dr. "Timothy Rust[,] confirmed th[is] diagnosis" and noted "'CLL can be associated with peripheral nervous system pathology similar to non-Hodgkin lymphoma, including a relatively high rate of CIDP.'" *Id.* (quoting Neurological Update at 58). At the time of his visit with Dr. Rust, petitioner "was having difficulty walking and . . . ha[d] muscle atrophy in his hands and burning pain in his feet." Resp. Rep. at 6 (quoting Neurological Update at 59). According to the Special Master, "[a]lthough most cases of CIDP develop insidiously, [it] can develop abruptly as in Mr. Hoffman's case." *Id.* at 5 (citing Expert

Report of Dr. Zurab Nadareishvili ("ZN Report"), Pet'r's Ex. 30 at 7, ECF No. 46-2); *see* Mot. for Review at 2 ("Petitioner's diagnosis is acute onset [CIDP].").

II. The Petition and Procedural History Before the Special Master

Although Mr. Hoffman now alleges his flu vaccine caused him to develop CIDP, he initially "alleged [it] . . . caused him to suffer GBS." SM. Dec. at 5; *see* Petition Against Secretary of Health and Human Services ("Pet.") at 5–7, ECF No. 1. As GBS is listed on the Vaccine Injury Table for the flu vaccination, Mr. Hoffman "sought compensation via the Vaccine Injury Table and adjudication through the special processing unit of the Office of Special Masters." *Id.* (citing Pet. at 5).

"The Secretary [of Health and Human Services] maintained that based upon the records from Dr. Eubank and Dr. Rust, Mr. Hoffman suffered from CIDP, not GBS. . . . [Thus,] resolution through the special processing unit seemed infeasible, [and] the case was reassigned." SM Dec. at 5; *see* Reassignment Order, ECF No. 26 ("On June 12, 2020, Respondent filed his Rule 4 Report, arguing there is evidence that Petitioner's injury may have been [CIDP] rather than [GBS] as alleged. . . . Pursuant to Vaccine Rule 3(d), the above-captioned case is hereby reassigned."). Following reassignment, Special Master Moran required petitioner to submit a "status report . . . indicating whether he intend[ed] to pursue a non-Table CIDP claim" because respondent's earlier-filed report indicated "that petitioner was ultimately diagnosed with CIDP, which is an exclusionary criterion for a GBS Table claim." *See* 2 July 2020 Order at 1, ECF No. 28. On 3 August 2020, petitioner filed a status report stating he "does intend to pursue an off-Table [CIDP] . . . case in this matter." Status Rep. at 1, ECF No. 29. On 17 September 2020, petitioner filed his Amended Petition explaining his "change in diagnosis to CIDP" and alleging "the vaccination administered actually caused the injuries complained of." Am. Pet. at 6, ECF No. 32.

A. The Special Master's Decision Denying Compensation

Following this reassignment and petition amendment, petitioner continued to file medical records and filed his expert report from Dr. Zurab Nadareishvili on 19 May 2021. *See* ZN Report. Special Master Moran then required respondent to file its expert report by 19 July 2021. *See* 20 May 2021 Non-PDF Order. Following an extension of time, respondent filed its expert report by Dr. Michael Wilson on 17 September 2021. *See* Expert Report of Dr. Michael Wilson ("Wilson Report"), ECF No. 53-1. On 22 August 2022, petitioner filed a motion for summary judgment, ECF No. 78-1, "respectfully ask[ing] this court to find that the vaccination at issue actually caused [his] injuries, and to conclude that [p]etitioner is thereby entitled to compensation." *Id.* at 3. In response, respondent alleged "petitioner has failed to meet his burden of proof to show a causal relationship between the flu vaccine and his CIDP," meaning petitioner's claim should be denied. Resp't's Sum. J. Resp. at 8, ECF No. 83. On 10 January 2024, Special Master Moran denied compensation. *See* SM Dec. at 2, 24. Special Master Moran concluded "Mr. Hoffman has based part of his claim on a level of proof (plausibility) that is lower than the required level of proof, which is preponderant evidence . . . [and u]nder the correct burden of proof, Mr. Hoffman has failed to show how a flu vaccine can cause CIDP. Thus, he is not entitled to compensation." *Id.* at 2.

In his decision, the Special Master presented a brief, undisputed account of petitioner's medical history. *See* SM Dec. at 2–5; *id.* at 2 n.2 ("[T]here are no disputes about what transpired in Mr. Hoffman's case."). The Special Master explained:

> Mr. Hoffman was diagnosed with low back pain on January 24, 2017. Exhibit 4 at 819, 862. This pain continued and Mr. Hoffman developed other problems for which he was admitted to Riverside Methodist Hospital. In Riverside Methodist Hospital, Mr. Hoffman underwent tests, including an EMG/NCS. Based upon the results, Mr. Hoffman's doctors diagnosed him with a neurologic disorder, Guillain-Barré syndrome. Exhibit 7 at 261, 876-81.
>
> Guillain-Barré syndrome is:
>
> (i) … an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.
>
> (ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. . . . AIDP [is] typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP . . . requires:
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> > (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
> >
> > (B) A monophasic illness pattern;
> >
> > (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
> >
> > (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
> >
> > (E) The absence of an identified more likely alternative diagnosis.

> . . .
>
> (v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.
>
> (vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP) . . . 42 C.F.R. § 100.3(c)(15).

SM Dec. at 2–4. Special Master Moran next discussed petitioner's change in diagnosis to CIDP. *Id.* at 4–5. Acknowledging "the etiology of CIDP is 'poorly understood,'" the Special Master quoted petitioner's expert Dr. Nadareishvili regarding "[a]n abundance of clinical and experimental research [that] has led to the conclusion that CIDP is . . . an autoimmune disease." *Id.* at 5 (quoting ZN Report at 9). The Special Master then undertook a review of the evidence in this case to determine whether petitioner had sufficiently alleged "the flu vaccine can provoke an autoimmune attack, which leads to CIDP." *Id.*

In his analysis, Special Master Moran acknowledged "Mr. Hoffman[] claims that a vaccine caused an injury not listed on the Vaccine Injury Table" and outlined the *Althen* test for off-table injuries: "A petitioner bears a burden 'to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.'" *Id.* at 7 (quoting *Althen v. Sec'y of Health & Hum Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Looking first to *Althen* prong one, the Special Master began by "determin[ing] the level of proof" required for petitioner's claim to succeed. *Id.* at 7. In doing so, Special Master Moran explained, "Mr. Hoffman recognizes that his burden of proof is preponderant evidence . . . [b]ut, Mr. Hoffman argues that a medical theory proposing a causal connection between a vaccine and an injury needs to be only plausible." *Id.* at 8 (citing Mot. for Review at 8, 17–18). Looking at two recent cases from the Court of Federal Claims and two from the Office of Special Masters, Special Master Moran concluded, "[a]n extensive analysis of this issue is not required . . . because within the last two calendar years, judicial officers have already held that the burden of proof for *Althen* prong one is persuasive [(i.e., preponderant)] evidence." *Id.* at 8–9 (first citing *Trollinger v. Sec'y of Health & Hum Servs.*, 167 Fed. Cl. 127, 137 (2023); then citing *Howard v. Sec'y of Health & Hum Servs.*, No. 16-159V, 2023 WL 4117370, at *4–*5 (Fed. Cl. May 18, 2023); then citing *Singleton v. Sec'y of Health & Hum Servs.*, No. 17-1474V, 2023 WL 3595653, at *20 (Fed. Cl. Spec. Mstr. May 23, 2023); then citing *J.D. v. Sec'y of Health & Hum Servs.*, No. 14-742V, 2022 WL 16543853, at *27 (Fed. Cl. Spec. Mstr. Aug. 31, 2022)).

Applying the preponderant standard, Special Master Moran "evaluate[d] Mr. Hoffman's proposed theory" to determine whether "the evidence surpasse[d] the correct threshold." *Id.* at 9. The Special Master's analysis of petitioner's theory began with a review of "non-binding precedents" providing guidance regarding "Mr. Hoffman['s] advance[ment of] molecular mimicry as a biologically plausible way that a flu vaccine can cause CIDP." *Id.* at 9–10.

Exploring decisions by the Federal Circuit, the Court of Federal Claims, and the Office of Special Masters, Special Master Moran noted "authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence." *See id.* at 10 (first citing *W.C. v. Sec'y of Health & Hum Servs.*, 704 F.3d 1352 (Fed. Cir. 2013); and then citing *Caves v. Sec'y of Health & Hum Servs.*, 100 Fed. Cl. 119 (2011), *aff'd sub nom.*, 463 Fed. App'x 932 (Fed. Cir. 2012); *Tullio v. Sec'y of Health & Hum Servs.*, No. 15-51V, 2019 WL 7580149, at *1214 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), *mot. for rev. denied*, 149 Fed. Cl. 448 (2020)); *id.* at 12 ("In accordance with precedents such as *W.C.*, *Caves*, [and] *Tullio* . . . the undersigned will look to see whether any evidence supports the theory that flu vaccine can cause CIDP.").

In reviewing petitioner's proffered evidence, the Special Master stated the "lack of understanding [regarding the cause of CIDP, which petitioner's expert acknowledged,] does not prevent Dr. Nadareishvili from proposing that the flu vaccine can cause CIDP via molecular mimicry . . . [even though r]eferences postulating molecular mimicry as contributing to CIDP appear scant in Mr. Hoffman's case." *Id.* at 14. The Special Master first discussed multiple articles regarding the "body's response to a malignant melanoma [and whether it] might lead to CIDP through molecular mimicry." *Id.* (first discussing M.D. Weiss et al., *Molecular Mimicry in Chronic Inflammatory Demyelinating Polyneuropathy and Melanoma*, 51 NEUROLOGY 1738 (1998), ECF No. 48-2; and then discussing Marinos C. Dalakas, *Pathogenesis of Immune-Mediated Neuropathies*, BIOCHIMICA ET BIPHYSICA ACT (17 June 2014), ECF No. 50-5; and Angelika F. Hahn et al., *Chronic Inflammatory Demyelinating Polyradiculoneuropathy*, *in* PERIPHERAL NEUROPATHY (Vol. 2) (2005), ECF No. 49-3). Special Master Moran likewise highlighted the Hahn article, which, after "review[ing] four studies, of which one (McCombe) was submitted as an exhibit here," concluded "a direct or indirect relationship between CIDP and [] preceding events remains to be established." *Id.* at 15 (citing Hahn et al., at 2224). Reported cases suggested the relation between immunization and CIDP is higher than chance, but the study lacked a control group for comparison. *Id.* (citing Hahn et al., at 2224).

The Special Master then reviewed two articles, neither of which, according to the Special Master, included reports of flu vaccines "preceding the onset of CIDP." *Id.* ("[In the McCombe study] no one reported receiving the flu vaccination . . . . Again, Bouchard did not report any instances of any vaccination preceding the onset of CIDP."). Indeed, in the Bouchard study, sixteen out of one hundred patients reported an infectious event within six weeks of their neurological symptoms, but none identified a vaccination as the event. *Id.* (citing C. Bouchard et al., *Clinicopathologic of Chronic Inflammatory Demyelinating Polyneuropathy* 498, 499 (1999), ECF No. 49-8. Dismissing a similar study in which "76 CIDP patients" completed a "questionnaire on average approximately six years after the onset of their CIDP," Special Master Moran cited the authors' concern regarding "draw[ing] firm conclusions from a questionnaire in which patients report their recurrences after vaccinations themselves." *Id.* at 15–16 (quoting Krista Kuitwaard et al., *Recurrences, Vaccinations, and Long-Term Symptoms in GBS and CIDP*, 14 J. OF PERIPHERAL NERVOUS SYSTEM 310, 312–15 (2009), ECF No. 50-3). Despite the authors reporting some possible link between vaccines, including the flu vaccine, and CIDP onset and symptoms, Special Master Moran noted "[t]he authors did not suggest any warnings

about [flu] vaccinations," leading the Special Master to conclude the "Kuitwaard [study] is an article that collects numerous case reports into a series" so is of little persuasive value. *Id.* at 16. Special Master Moran then dismissed another case report other researchers previously found to "not contribute to the weight of mechanistic evidence," *id.* at 17, especially as "case reports often do not receive much consideration as evidence of causation." *Id.* (citing *K.O. v. Sec'y of Health & Hum. Servs.*, No. 13-472V, 2016 WL 7634491, at *11–*12 (Fed. Cl. Spec. Mstr. July 7, 2016)). In the report, a patient was diagnosed with CIDP after receiving a flu vaccination, however, "the development of CIDP after influenza vaccination ha[d] not been previously reported," so the Special Master afforded the study little weight. *Id.* (citing J.M. Brostoff et al., *Post-influenza vaccine chronic inflammatory demyelinating polyneuropathy* at 229, (2008), ECF No. 48-5). The Special Master further concluded "Dr. Nadareishvili does not add much on CIDP . . . . [So a]t the end of the day, there is not sufficient evidence to support a finding that molecular mimicry is a *persuasive theory* to explain how flu vaccines might cause CIDP." *Id.* at 17–18 (emphasis added) ("Without having some well-informed ideas of the target antigen and how an attack on the antigen leads to CIDP, it is difficult to accept, on a more likely than not basis, the proposition that the flu vaccine contributes to a poorly understood process.").

Turning briefly to petitioner's analogization between CIDP and GBS, the Special Master acknowledged "Mr. Hoffman's attempted method of proof is legitimate . . . [as] [p]etitioners may try to establish their cases through circumstantial evidence." *Id.* at 19 (citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006)). Special Master Moran likewise recognized "GBS is both similar and different from CIDP." *Id.* For instance, "both conditions are believed to involve an attack on the myelin in the peripheral nerves," but "GBS is a monophasic disease and CIDP is a chronic disease." *Id.* Further, according to Special Master Moran, the "etiology of GBS is coming into focus," including via "some epidemiological studies . . . discover[ing] a slight increase in the incidence of GBS among people receiving a flu vaccine." *Id.* (citing 80 Fed. Reg. 45132, 45145–46 (July 29, 2015)); *id.* at 20 ("[T]he Secretary [of Health and Human Services] found that the evidence and policy grounds support a proposal to associate the flu vaccine with GBS on the Vaccine Injury Table."). Per the Special Master, however, "the data that allowed the Secretary [of Health and Human Services] to associate the flu vaccine with GBS [for purposes of listing it on the Vaccine Injury Table] is lacking for CIDP . . . [meaning] a finding that the flu vaccine can cause CIDP because [it] can cause GBS . . . is at least one step too far to be persuasive." *Id.* at 20 ("There is neither the quality nor the quantity of evidence regarding any causes of CIDP."). Thus, after evaluating recent similar cases in the Office of Special Masters, Special Master Moran concluded, although "molecular mimicry . . . may very well be . . . a biologically plausible theory to explain how the flu vaccine might cause GBS," "biological plausibility is not the evidentiary standard" under *Althen* prong one, meaning "Mr. Hoffman's evidence fails to measure up." *Id.* at 23.

III. The Parties' Expert Reports

A. Petitioner's Expert Report from Dr. Zurab Nadareishvili

As noted *supra*, petitioner filed his expert report from Dr. Zurab Nadareishvili on 19 May 2021. *See* ZN Report. Dr. Nadareishvili is an Associate Professor of Neurology at George Washington University School of Medicine and Health Sciences and serves as a Medical

Director of the Stroke Program at Virginia Hospital Center. Curriculum Vitae of Dr. Nadareishvili at 1, ECF No. 46-3. Dr. Nadareishvili treats between 3 and 5 CIDP patients a year and treats approximately 1 GBS patient per month. ZN Report at 2.

In his report, Dr. Nadareishvili asserted, "[i]t is my opinion that, to a reasonable degree of medical probability, [] Mr. Hoffman suffered from acute onset [CIDP], that he experienced the onset of that condition about thirteen days from the date of vaccination, and that the vaccination at issue was a substantial factor in the causation of Mr. Hoffman's injured condition that has persisted . . . to this day." *Id.* at 1. Specifically, Dr. Nadareishvili stated, "CIDP is an immune-mediated neuropathy. . . . In studying the potential immune mechanisms that trigger the development of autoimmune responses to self, researchers focus on environmental triggers of autoimmunity such as infections and vaccinations, and have developed a few different theoretical mechanisms to understand this process." *Id.* at 9–10. Dr. Nadareishvili then listed four ways a vaccine can lead to an autoimmune response, each having been used to explain the pathogenesis of GBS and CIDP. *Id.* at 10–11. He stated, "[r]esearch has most consistently supported molecular mimicry as the dominant mechanistic model to explain the aberrant immune responses that cause peripheral nerve injury like that seen in this case." *Id.* at 11. Dr. Nadareishvili further elaborated on molecular mimicry and how it specifically occurs in relation to vaccines:

> Infectious agent[s] or vaccine[s] . . . may carry elements that are similar enough to amino acid or glycan sequence[s] or structure[s] to self-antigens that the pathogen[s] or vaccine[s] act[] as a self-'mimic'. Termed 'molecular mimicry', T or B cells that are activated in response to the . . . vaccine are also cross-reactive to self and lead to direct damage and further activation of other arms of the immune system.

Id. at 10. Dr. Nadareishvili then described how vaccine injury is linked to CIDP through autoantibodies:

> Research indicates that autoimmunity in CIDP is most likely mediated by antibodies directed against myelin antigens, along with autoreactive T cells and macrophages that invade the myelin sheath, axonal membranes and/or the nodes of Ranvier. Antibodies against myelin . . . antigens have been found in the serum of CIDP patients. Experimental models have shown that these autoantibodies from CIDP patients directed against myelin . . . antigens can produce neuropathic changes resembling CIDP in experimental animals.

Id. at 11–12. Dr. Nadareishvili stated as "proof of principle" of molecular mimicry in CIPD cases, "[m]elanoma vaccines can express gangliosides . . . in the peripheral nerves and [] patients with melanoma and CIDP also have anti-ganglioside antibodies against gangliosides expressed." *Id.* at 12. Conceding, "the precise pathogenesis of [CIDP] is not [] fully delineated," Dr. Nadarehivili stated, "there are data points that support the thesis of molecular mimicry causing CIDP following an immune challenge." *Id.* at 12. Finally, Dr. Nadareishvili discussed why GBS is more frequently linked to vaccination than CIDP:

> It needs to be emphasized that A-CIDP diagnosis is always made in retrospect as there are no clinical, electrodiagnostic, or biological markers that allow distinction between A-CIDP and GBS in the acute phase. . . . Whereas GBS is frequently linked to a preceding triggering event such as infection or vaccination, this association is less apparent in CIDP due to the insidious onset and evolution of CIDP and the common delay in making the diagnoses, which is on average 6-12 months from the onset of symptoms, so patients may no longer recall prodromal events.

Id. at 8.

B. Respondent's Expert Report from Dr. Michael Wilson

Respondent filed its expert report by Dr. Michael Wilson on 17 September 2021. *See* Wilson Report. Dr. Wilson is an Associate Professor of Neurology at the University of California, San Francisco. Curriculum Vitae of Dr. Wilson at 1, ECF No. 53-12. Dr. Wilson "ha[s] a weekly clinic of 5–7 patients" and "AIDP and CIDP are frequently part of [his] differential diagnoses." Wilson Report at 1.

Dr. Wilson did not dispute "petitioner has CIDP that became symptomatic temporally after his COPD exacerbation and administered vaccinations" but stated "there is very weak evidence for any association between CIDP and influenza vaccinations" and "petitioner has pre-existing [CLL] that puts him at significantly increased risk for CIDP." *Id.* at 4. Specifically, Dr. Wilson stated AIDP, which is a subtype of GBS, is most often triggered by viruses but noted there are "vaccine-induced cases, most notably from the 1976 swine influenza vaccine." *Id.* at 3. He continued, CIDP sometimes "presents in a more insidious fashion than AIDP, but can also have a more abrupt onset, as in the petitioner's case, thus making it difficult to distinguish from AIDP early on in the disease course." *Id.* at 4 (citations omitted). Turning to CIDP in particular, Dr. Wilson explained, the Institute of Medicine's (IOM) 2012 report on the adverse effects of vaccines assessed "the mechanistic evidence regarding an association between influenza vaccine and CIDP as weak." *Id.* (internal quotations omitted). Dr. Wilson noted the IOM's 2012 report concluded "the evidence is inadequate to accept or reject a causal relationship between influenza vaccine and CIDP." *Id.* (internal quotations omitted). Further, regarding petitioner's medical history, Dr. Wilson stated "much of the literature [Dr. Nadareishvili] cites posits a link between anti-ganglioside bodies being cross-reactive against certain influenza antigens, and antigens displayed on myelin surrounding peripheral nerves. However, petitioner was tested for the presence of anti-ganglioside antibodies, and this testing was negative." *Id.* at 4–5.

C. Expert Rebuttal and Supplemental Reports

In his Reply Report for petitioner filed 11 January 2022, Dr. Nadareishvili responded to Dr. Wilson: "At no point did [Dr. Wilson] state that the theoretical explanation propounded in my earlier report was unviable as a scientific explanation." Reply of Dr. Nadareishvili (ZN Reply) at 2, ECF No. 61-2. Dr. Nadareishvili likewise disputed Dr. Wilson's remark CLL can lead to CIDP:

> Dr. Wilson's insinuation that petitioner's co-morbid pre-existing conditions were the cause of his CIDP is misleading, as no single study thus far has postulated a causal relationship between CLL and CIDP. . . . His report did not cite to literature that explained how CLL could cause, or even contribute to causing CIDP. . . . As was already mentioned the Briani letter to the editor showed extremely low 0.37% [] prevalence of CIDP in CLL, and no causality or even association between these two conditions can be claimed based on this study as there was no control group without CLL to compare with. Indeed, even the authors of [the] Briani [letter] [] declined to postulate a causal relationship between CLL and CIDP.

Id. at 5. Respondent filed its Supplemental Expert Report by Dr. Wilson on 13 March 2022, in which Dr. Wilson emphasized "there is vanishing[ly] little evidence in the scientific and medical literature and from the [petitioner's] clinical test results . . . to undergird this speculation that petitioner's influenza vaccination actually did trigger his CIDP." Michael R. Wilson Expert Report (Suppl. Wilson Rep.) at 1, ECF No. 63-1.

IV. Petitioner's Motion for Review and Respondent's Arguments

On 9 February 2024, petitioner moved for review of the Special Master's Decision Denying Compensation. *See* Mot. for Rev. Disputing the level of proof of causation required by the Special Master, petitioner asserts, "[b]inding Federal Circuit precedent is clear that [p]etitioner was bound to provide, to a preponderance of the evidence in the individual case, a reasoned, *plausible explanation* for how the vaccine at issue *can* cause [p]etitioner's injury, based on the scientific evidence that is available and filed into the record. . . . Here, the Special Master evaluated the evidence based on a faulty standard of proof." *Id.* at 12 (first emphasis added). In other words, according to petitioner, "[t]he applicable law in the Vaccine Program contemplates preponderant proof of biological plausibility as the sufficient proof for a medical theory, not preponderant proof of the theory itself." *Id.* at 10; *see also* Tr. at 18:14–18 ("[PETITIONER:] We would say that the distinction is what must be proved versus what is necessary to prove it, that plausibility is what must be proved, that it must be proved through preponderant evidence more likely than not that it is plausible."). In response, respondent argues, contrary to petitioner's assertion, "the evidence must establish more likely than not that the vaccine can cause an injury in general." Resp't's Resp. at 3. After reviewing the parties' arguments, the Court ordered supplemental briefing regarding the relationship between the dispute in this case and the Court's analysis in its previous decision, *J. v. Sec'y of Health and Hum Servs.*, 155 Fed. Cl. 20 (2021), on 18 March 2024. *See* 18 Mar. 2024 Order, ECF No. 94. On 2 April 2024, respondent filed its Supplemental Brief, (Resp't's Suppl. Br., ECF No. 95), and petitioner filed his Supplemental Brief the next day, *see* Pet'r's Suppl. Br., ECF No. 96. The Court held oral argument on Petitioner's Motion for Review on 20 June 2024 in Washington, DC. *See* 3 Apr. 2024 Order, ECF No. 97.

Specifically, in his Motion for Review, petitioner argues the Special Master erred in two related ways: (1) "by applying incorrect legal standards to the evaluation of general causation, requiring empirical evidence and scientific evidence . . . for a condition [for] which scientific knowledge is limited[;]" and (2) "by applying an incorrect legal standard to the assessment of [p]etitioner's medical theory." Mot. for Review at 1. In other words, petitioner accuses the

Special Master of using "an incorrect analytical framework, which elevated the burden of proof on general causation." *Id.* at 3. At oral argument, the parties confirmed there are no factual disputes at this stage of the litigation. *See* Tr. at 5:13–20 ("THE COURT: So before we get into the agenda, can both parties [] confirm that at this stage in the petition for review [] there are no factual issues that are in dispute? [PETITIONER:] None were raised in the Motion, Your Honor. THE COURT: And the Respondent agrees? [RESPONDENT:] That is correct.").

As to petitioner's first allegation, petitioner explains "[t]he first prong of the *Althen* standard is the element of general causation, which considers the more abstract, theoretical issue of whether the vaccine *can cause* the particular injury alleged, by postulating a medical theory of causation." Mot. for Review at 4. Per petitioner, "[t]he law required [p]etitioner to prove by a preponderance of the evidence filed in this case that his medical theory was biologically plausible[] and reliable within the context of available medical knowledge. Instead, the Special Master held [p]etitioner responsible to prove the theory with empirical evidence, and to explain specific mechanisms . . . to prove precisely how the vaccination . . . damaged[] [p]etitioner's peripheral nervous system." *Id.* at 4–5. Petitioner takes particular issue with the Special Master determining "the lack of 'definitiveness'" in petitioner's theory required a denial of compensation. *Id.* at 5. Petitioner argues he met his burden to show—either via direct or circumstantial evidence—the "vaccination *could* cause [his] injury, and then explain how the facts of" his "case aligns with that explanation." *Id.* at 6, 13 ("The point of allowing circumstantial evidence in the preponderance standard of proof is that, when taken together, the various datapoints combine to support the medical theory."). Citing multiple Federal Circuit cases, *see id.* at 7–8 (citing, for example, *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); then citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006); and then citing *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)), petitioner argues "the judges of the Court of Federal Claims have reversed special master decisions which applied aberrant analysis that would require petitioners to provide *specific pathologic mechanisms or identification of antibody-epitope relationship*." *Id.* at 9 (citing *Stitt v. Sec'y of HHS*, 2013 U.S. Claims LEXIS 780, *30-31 (2013); then citing *Patton v. Sec'y of Health & Hum. Servs.*, 157 Fed. Cl. 159, 168 (2021)). Indeed, petitioner points to *Sharpe*, in which the Federal Circuit explained, "the Special Master should not have been concerned with what 'future research' may show but rather with the research presented in the record" because "[t]he Vaccine Injury Program, after all, is designed to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Id.* at 9 (quoting *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072, 1083 (Fed. Cir. 2020) (internal quotations omitted)). Ultimately, according to petitioner, the "applicable law . . . contemplates preponderant proof of biological plausibility as the sufficient proof for a medical theory, not preponderant proof of the theory itself." *Id.* at 10.

Regarding his related second allegation, Mr. Hoffman asserts a petitioner "satisfies the 'can cause' element by presenting a 'medically plausible theory.'" *Id.* at 17. While acknowledging certain recent "cases have seemed to diverge from this established plausibility standard," petitioner points to several Court of Federal Claims cases "harmoniz[ing the divergent cases] with the longstanding [plausibility] precedent" and argues no recent decision has changed the "nearly 30 years of Federal Circuit precedent on the standard for *Althen*'s prong 1." *Id.* at 18–19. In his Supplemental Brief, petitioner reaffirms his argument, "it is a category error to

conflate the general requirement for the quantity of evidence necessary to prove any component of the prima facie case [(i.e., preponderant evidence)] with the qualitative metric for evaluating the quality of a medical theory, which has remained biological plausibility." Pet'r's Suppl. Br. at 2. Petitioner continues, "[t]he *can cause* standard of biological plausibility is the correct legal standard" for general causation, *id.*, meaning the Court was correct in *J. v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 20 (2021) "that the first prong of *Althen* was satisfied . . . when petitioner's expert presented a 'biologically plausible' theory." *Id.* at 3–4 (quoting *J.*, 155 Fed. Cl. at 42–43) (cleaned up).

Respondent disputes petitioner's assertion *Althen* prong one is subject to a plausibility standard. Specifically, respondent alleges "[t]he preponderance standard applies to each *Althen* prong individually." Resp't's Resp. at 3; *see* Tr. at 22:4–8 ("[RESPONDENT:] Petitioner's medical theory must be preponderantly supported or more likely than not based on persuasive and reliable evidence. So the preponderant standard is a quantum of evidence. We typically refer to it as 51 percent."). According to respondent, "[t]he plausibility argument has been repeatedly made on appeal by petitioners in recent years, and it has been repeatedly rejected by both the Court of Federal Claims and the Federal Circuit." Resp't's Resp. at 8 (citing *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014); then citing *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1350, 1360 (Fed. Cir. 2019); and then citing *W.C.*, 704 F.3d at 1356). Respondent reiterated its arguments in its Supplemental Brief, *see* Resp't's Suppl. Br., in which it argues "the Federal Circuit has repeatedly stated . . . that the preponderant evidence standard applies to each *Althen* prong individually." *Id.* at 6. Indeed, in discussing the Court's previous decision in a similar case, *J. v. Sec'y of Health & Hum. Servs.*, which respondent acknowledges "suggested that biological plausibility was the appropriate evidentiary standard . . . under *Althen* prong one," *see id.* at 5 (citing *J.*, 155 Fed. Cl. at 42–44), respondent contends, "[i]f the Federal Circuit had intended that a petitioner could satisfy *Althen* prong one by merely identifying a biologically plausible medical theory, it would have affirmatively articulated such a standard." *Id.* at 6. Thus, respondent alleges "the Court misread the vaccine case law in" *J.* *See* Tr. at 8:3–11.

Further, in response to petitioner's specific arguments, respondent argues the Special Master correctly "required petitioner to provide preponderant evidence that his proffered medical theory of molecular mimicry was sound and reliable in this case," and petitioner failed to do so. Resp't's Resp. at 11–12. Indeed, respondent contends "Dr. Nadareishvili was unable to offer legally sufficient evidence," "there is too little evidence to support a causal link between the flu vaccine and CIDP," and "[t]he Federal Circuit has previously rejected . . . molecular mimicry as being too generic to be persuasive in a specific case." *Id.* at 12 (citing *W.C.*, 704 F.3d 1352). Further, contrary to petitioner's contention, respondent alleges "the Special Master correctly evaluated the circumstantial evidence" and—similar to other recent Office of Special Master cases—"concluded that CIDP and GBS are highly 'distinguishable.'" *Id.* at 14–15.

V. Legal Standards

A. The Court's Standard of Review of a Special Master's Decision

The Vaccine Act provides this court jurisdiction to review a Special Master's decision upon timely motion of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing the record of the proceedings before the Special Master, the Court may: (1) "uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision;" (2) "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law;" or (3) "remand the petition to the special master for further action in accordance with the court's direction." *Id.* § 300aa-12(e)(2). "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Saunders v. Sec'y of Dept. of Health & Hum. Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting *Munn v. Sec'y of Dept. of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

It is not the Court's role "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871). The Court also does "not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." *Id.* (quoting *Munn*, 970 F.2d at 871). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009).

B. The Standard of Causation in Vaccine Cases

"A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1341 (Fed. Cir. 2010) (citing 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)). "A petitioner can show causation under the Vaccine Act in one of two ways": (1) "by showing that she sustained an injury in association with a vaccine listed in the Vaccine Injury Table," in which case "causation is presumed"; or (2) "if the complained-of injury is not listed in the Vaccine Injury Table . . . the petitioner may seek compensation by proving causation in fact." *Id.* at 1341–42 (internal citations omitted). Vaccine cases employ a burden shifting standard: "[o]nce the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine." *Id.* at 1342 (citing *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010); 42 U.S.C. § 300aa-13(a)(1)(B)).

"When a petitioner has suffered an off-Table injury . . . [the Federal Circuit] has established the following test for showing causation in fact under the Vaccine Act:"

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Broekelschen, 618 F.3d at 1345 (quoting *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Under the first prong of *Althen*, "[a] petitioner must provide a 'reputable medical or scientific explanation' for its theory." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, [the explanation] must still be 'sound and reliable.'" *Id.* (quoting *Knudsen ex rel. Knudsen v. Sec'y of Dept. of Health & Hum. Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Petitioners "need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act." *Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009). Where such evidence is introduced, it must not be viewed "through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. For satisfying the second *Althen* prong, "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280). Lastly, "the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

VI. Whether the Special Master Erred in Requiring Persuasive Evidence of a Persuasive Theory Under *Althen* Prong One

In rejecting petitioner's proffered theory of causation, Special Master Moran concluded "'biological plausibility' is not the evidentiary standard" under *Althen* prong one. SM Dec. at 23. Instead, the Special Master required "persuasive evidence," *id.* at 8, of "a persuasive theory." *Id.* at 9; *see id.* at 8 (noting "persuasive" is higher on the "evidentiary scale" than "plausible"). Respondent agrees, noting "both the Court of Federal Claims and the Federal Circuit . . . ha[ve] made clear that 'simply identifying a "plausible" theory of causation is insufficient for a petitioner to meet [his] burden of proof.'" Resp't's Resp. at 8 (quoting *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (additional citations omitted)); *see* Tr. at 24:2–7 ("[RESPONDENT:] [If] all Petitioner had to provide was preponderant evidence to satisfy a plausible theory . . . very likely it would be very general . . . [s]o that's why a plausible theory is not sufficient."). In response, petitioner contends "the Special Master erred by applying an incorrect legal standard to the assessment of [p]etitioner's medical theory." Mot. for Review at 1. According to petitioner, he "must provide preponderant proof of every component of . . . [his] case, including preponderant proof that the medical theory relied upon to prove causation is *plausible*." *Id.* at 15 (emphasis added); *see* Tr. at 18:8–14 ("THE COURT: So for Petitioner first . . . you argue on page 10 the first *Althen* prong contemplates preponderant proof of biological plausibility as the sufficient proof for a medical theory . . . is that correct? [PETITONER:] Yes, sir."). The parties thus do not dispute petitioners bear the burden of proving all *Althen* prongs, including prong one, by preponderant evidence, *see* Tr. at 17:25–18:6 ("THE COURT: Do both parties then also agree that the test requires preponderant evidence of a medical theory connecting the relevant vaccine to the kind

of injury suffered? [PETITIONER:] Yes, sir. THE COURT: [Respondent?] [RESPONDENT:] Agreed, Your Honor."), but they disagree as to the required quality of petitioners' proffered medical theory. Tr. at 18:8–19:5 (petitioner agreeing "the first *Althen* prong contemplates preponderant proof of biological plausibility"); Tr. at 8:8–11 ("THE COURT: Does Respondent believe, then, as the Special Master put it in this case, Petitioner must present a persuasive theory? [RESPONDENT:] That is correct."); *compare* Resp't's Suppl. Br. at 5 ("[The Federal Circuit's] decision[s] cannot and should not be ready to endorse the notion that the correct standard under *Althen* prong 1 is mere biological plausibility."), *with* Mot. for Review at 15 (stating petitioners must provide "preponderant proof that the[ir] medical theory . . . is plausible"). While this dispute mirrors that of the parties in the Court's previous *J.* case, the Court revisits all relevant statutes and caselaw to determine the appropriate standard under *Althen* prong one anew. *See J. v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 20, 40–43 (2021); *see also* Tr. at 17:3–7 ("[THE COURT:] [D]oes Petitioner agree with the Court's holding in [*J.*] that *Althen* prong one requires a biologically plausible theory linking the vaccine to the injury? [PETITIONER:] Yes, sir."); *see also* Tr. at 12:18–14:5 ("[THE COURT:] So . . . Respondent would agree that there's no Federal Circuit precedential decision that has changed any of the reasoning in [*J.*]? [RESPONDENT:] That is correct."). Notably, at oral argument, the parties agreed "if the Court were to hold . . . that the standard [under *Althen* prong one] is plausibility," the best path would be "to remand and [] allow a full reevaluation of all the record evidence under this standard." Tr. at 15:24–17:2; *see also* Tr. at 17:8–11 ("THE COURT: If the holding [from *J.*] were to be applied in this case, does that warrant granting [p]etitioner's motion for review and then vacating and remanding? [PETITIONER:] Yes, sir.").

The first prong of *Althen* requires a petitioner to provide "a medical theory causally connecting the vaccination and the injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citation omitted). The theory need not be corroborated by medical literature or epidemiological evidence. *See Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006); *Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Hum. Servs.,* 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("A trial court . . . [need] not [] evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence."). Several Federal Circuit decisions have shed light on the meaning of this prong. In *Andreu*, for example, the petitioners "argue[d] that they satisfied all three prongs of the *Althen* test by . . . setting forth what even the government's expert agreed was a 'biologically plausible' theory explaining how toxins in the whole cell pertussis vaccine could cause seizures." *Andreu,* 569 F.3d at 1375. Agreeing with the petitioners, the Federal Circuit stated the petitioners "met the first . . . prong[] of the *Althen* test" because their expert "presented a 'biologically plausible' theory establishing that . . . [the] pertussis vaccine can cause seizures." *Id.* In *Andreu*, referencing *Althen*, the Federal Circuit accordingly cautioned against "impermissibly rais[ing] a claimant's burden under the Vaccine Act" as doing so would frustrate "the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id.* at 1378 (quoting *Capizzano*, 440 F.3d at 1325–26) (internal quotations omitted); *see Althen*, 418 F.3d at 1280 (noting it is "the purpose of the Vaccine Act[]" to "allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body"). Although the Special Master in the instant case cited *Andreu*, *see* SM Dec. at 7, he did so for an unrelated proposition. Respondent, on the other hand, conceded *Andreu* "does say that [prong one] was met" by a plausible theory. *See* Tr. at 41:12–24.

Similarly, in *Kottenstette*, the special master ruled in favor of the petitioner, finding *Althen* prong one was satisfied as there was "a medical theory causally connecting the vaccination and the injury." *Kottenstette v. Sec'y of Health & Hum. Servs.*, 861 Fed. App'x. 433, 437 (Fed. Cir. 2021) (internal quotations omitted). On appeal, the Federal Circuit held "the [] special master applied the correct legal standard." *Id.* at 440. Indeed, the Federal Circuit stated "[t]he [] special master's statement that 'medical probability means biological credibility rather than specification of an exact biological mechanism . . . correctly recites this court's statement in several precedential cases that proof of causation does not 'require identification and proof of specifical biological mechanisms[.]'" *Id.* at 440–41 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994); then citing *Simanski v. Sec'y of Health & Hum. Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012)). The Federal Circuit therefore approved of the special master's application of a "biologic[al] credibility" standard to petitioner's medical theory of causation. *Id.* The Federal Circuit has thus said a biologically credible, or plausible, theory is sufficient under *Althen* prong one. *Id.*; *Andreu*, 569 F.3d at 1375; *see Plausible*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (3rd ed. 2021) ("4a: superficially worthy of belief: credible"); *Credible*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (3rd ed. 2021) ("1: capable of being credited or believed").

In holding "the burden of proof for *Althen* prong one is persuasive evidence" of a "persuasive theory," rather than a biologically plausible theory, however, the Special Master cited the Federal Circuit's 2019 decision in *Boatmon*. *See* SM Dec. at 9 (citing *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351 (Fed. Cir. 2019)); *see also* Resp't's Resp. at 3 (noting *Boatmon* reiterated "that 'a "plausible" or "possible" causal theory does not satisfy the standard"). In *Boatmon*, the Federal Circuit discussed "petitioners' burden to prove actual causation" in "off-Table cases." *Boatmon*, 941 F.3d at 1359. In doing so, the Federal Circuit noted the "burden to prove actual causation [is] . . . a preponderance of the evidence." *Id.* (citation omitted). This, according to the Federal Circuit, necessitates proffering a "sound and reliable" theory of causation. *Id.* (quoting *Knudsen*, 35 F.3d at 548–49) (internal quotations omitted). The Federal Circuit in *Boatmon* therefore took issue with the special master "deviat[ing] from the correct 'reputable,' 'sound and reliable' standard and articulat[ing] a 'reasonable' standard." *Id.* Thus, according to *Boatmon*, *Althen* prong one requires petitioners "show by a preponderance of the evidence" their proposed "theory . . . is a sound and reliable medical theory of causation." *Id.* at 1362. To the extent the *Boatmon* court "reiterated that a 'plausible' . . . theory" is insufficient and discussed "prov[ing] all three *Althen* prongs by a preponderance of the evidence," *id.* at 1355, 1360, the Federal Circuit was "analyzing the overall standards for 'petitioners' burden to prove actual causation[,'] not [the] standard for [petitioner's theory required by] *Althen* [prong] one." *J. v. Sec'y of Health and Hum Servs.*, 155 Fed. Cl. 20, 43 (2021) (quoting *Boatmon*, 941 F.3d at 1360). Indeed, as further explained by this Court in *J.*, "[i]n the section of the *Boatmon* opinion where the Federal Circuit rejected a merely 'plausible' theory as sufficient to establish causation, the Federal Circuit was specifically analyzing the overall standard for 'petitioners' burden to prove actual causation by a preponderance of the evidence in off-table cases,' not a standard for *Althen* element one . . . . The *Boatmon* court reserved a separate section to discuss *Althen* element one, where the court used 'a sound and reliable medical theory of [causation]' as the legal standard to review the special master's decision." *Id.* (quoting *Boatmon*, 941 F.3d at 1360–62). In other words, *Boatmon* merely

reiterated the familiar rule petitioners must present preponderant evidence of a "sound and reliable medical theory," *Boatmon*, 941 F.3d at 1360, which *Andreu* referred to as "a 'biologically plausible' theory."[2] *Andreu*, 569 F.3d at 1375; *see also Olson v. Sec'y of Health & Hum. Servs.*, 758 Fed. App'x. 919, 922 (Fed. Cir. 2018) (citing *Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018) (requiring petitioners "show by preponderant evidence each of the requirements set forth in *Althen*") (cleaned up)). It did not, as mischaracterized by the Special Master,[3] impose a requirement petitioners must "present a persuasive theory." SM Dec. at 8.

Although respondent cites other Federal Circuit cases, such as *Moberly* and *LaLonde*, in support of its argument "[t]he preponderance standard appl[ying] to each *Althen* prong individually" means "it is insufficient for petitioner to posit a merely plausible theory," respondent misunderstands the rule set forth in these decisions. Resp't's Resp. at 3. In *Moberly,* the petitioner—like petitioner here—argued "the special master imposed a heightened burden of proof by requiring a showing of causation to the level of 'scientific certainty' rather than by a preponderance of the evidence." *Moberly ex re. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir 2010). There, however, the petitioner contended the appropriate test was "whether . . . [the] condition was 'likely caused'" by the relevant vaccine. *Id.* The Federal Circuit rejected this, stating the petitioner's proposed test is "closer to proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" than the appropriate "'more likely than not' standard." *Id.* Keying in its previous analysis of *Althen* prong one in *Andreu*, the Federal Circuit then recognized a theory of general causation "should . . . be[] credited" when it is a "biological[ly] plausibl[e] . . . theory." *Id.* at 1325. In other words, as in *Boatmon*, *Moberly* acknowledged petitioners can satisfy *Althen* prong one via a biologically plausible theory, so long as they present preponderant evidence (i.e., satisfy the "more likely than not" standard) of this theory. *Id.* Notably, respondent conceded at oral argument *Moberly* "seems to recognize . . . that when there is a biologically plausible theory, it is proper for the Special Master to credit it as sufficient for prong one." *See* Tr. at 72:1–11 (the Court discussing *Moberly* with respondent). Likewise, in *LaLonde*, the Federal Circuit stated petitioners must "demonstrate that the vaccine more likely than not *caused* the condition alleged," *Lalonde v. Sec'y of Health & Hum. Servs.*,

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[2] To the extent respondent alleged at oral argument the term "'sound and reliable' is the same as 'persuasive," *see* Tr. at 62:4–63:7, there is no indication *Boatmon* intended to depart from previous Federal Circuit precedent, such as *Andreu*, which required only a plausible medical theory. Indeed, respondent conceded there is no other "Federal Circuit case law . . . clarify[ing] that . . . 'persuasive' is the same as 'sound and reliable.'" *See* Tr. at 63:16–24; *see also* Tr. at 63:9–15 ("[PETITIONER:] I disagree ['sound and reliable' means 'persuasive.']").

[3] In his decision, despite relying on *Boatmon* to conclude "[p]roof at merely a plausible level is insufficient as a matter of law," Special Master Moran failed to discuss the meaning of *Boatmon*'s "sound and reliable" terminology and, indeed, did not even cite pages 1361 and 1362 of *Boatmon*, in which the Federal Circuit conducted its *Althen* prong one analysis. *See* SM Dec. at 9, 21; *Boatmon*, 941 F.3d at 1360–62 (discussing whether the petitioners' theory "is a sound and reliable medical theory as required by *Althen* prong one"). Respondent conceded this at oral argument. *See* Tr. at 69:17–70:5 ("THE COURT: So did the Special Master in this case, in *Hoffman*, apply a sound and reliable standard? [RESPONDENT:] Well, yes. THE COURT: And did Special Master Moran say that? [RESPONDENT:] In those words specifically . . . maybe not."); Tr. at 70:18–25 ("THE COURT: You would agree, though, that [Special Master Moran] did not cite to 1362 of *Boatmon*? He cited to 1360. [RESPONDENT:] That may, in fact, be the case, Your Honor. . . . THE COURT: I think it's just 1360, which . . . seems to be not necessarily related to prong one."). Instead, Special Master Moran cited only to the Federal Circuit's discussion of "the petitioners' burden to prove *actual causation*." *See* SM Dec. at 9 (citing *Boatmon*, 941 F.3d at 1351, 1360) (emphasis added).

746 F.3d 1334, 1339 (Fed. Cir. 2014) (emphasis added), while also acknowledging *Althen* requires "petitioner[s] to show . . . the medical plausibility of [their] theory of causation. . . ." *Id.* at 1340 (citing *Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 13555, 1365 (Fed. Cir. 2012)). Thus, the *LaLonde* court similarly distinguished between the burden of proof linking vaccine to injury—preponderant evidence—from the standard of certainty required of petitioner's theory—plausibility. *See id.* *Moberly* and *LaLonde*, like *Boatmon*, therefore stand for the proposition that to satisfy *Althen* prong one petitioners must provide preponderant evidence linking the vaccine received to the injury suffered via a biologically plausible theory. *Moberly*, 592 F.3d at 1322, 1325; *see also Boatmon*, 941 F.3d at 1359, 1362.[4]

The Federal Circuit's caselaw from the last several decades thus makes clear a petitioner can satisfy *Althen* prong one by "setting forth . . . a 'biologically plausible' theory" of general causation. *Andreu*, 569 F.3d at 1375; *see also Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1380 (Fed. Cir. 2015) (describing medical plausibility as follows: the "vaccination could . . . in theory" cause the injury); *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072, 1083 (Fed. Cir. 2020) (explaining a medically plausible theory must merely "demonstrat[e] that [the] vaccine 'can' cause" the injury at issue)[5]; *see also* Tr. at 73:25–74:24 ("[THE COURT:] Well, what precedential Federal Circuit decision directly addresses prong one . . . with a standard different than plausibility[?] . . . [RESPONDENT:] Well, *Althen* . . . THE COURT: Any other[s?] . . . [RESPONDENT:] [B]eyond that . . . I don't know . . ."). The parties agree petitioner must do so "by a preponderance of the evidence" as required by *Boatmon*, *see supra*; *see Olson*, 758 Fed. App'x. at 922 (citing *Oliver*, 900 F.3d at 1361 (requiring petitioners "show

[4] On 20 June 2024, minutes before oral argument in this case, the Federal Circuit issued its non-precedential decision in *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 23-1321 (Fed. Cir. June 20, 2024). As the Court and parties discussed this opinion at oral argument, *see* Tr. at 74:25–78:5 (discussing *Kalajdzic*), the Court takes judicial notice of the decision. *See* Tr. at 77:10–79:19 (petitioner noting the Federal Circuit in *Kalajdzic* commits "a category error" between "the level of evidence . . . needed to prove the medical theory . . . [and] what makes a theory legitimate"); Tr. at 75:4–16 (respondent explaining *Kalajdzic* "affirmatively endorsed the preponderant evidence standard under *Althen* prong one"). The government subsequently filed a notice of additional authority on 3 July 2024 to "bring the Court's attention to specific aspects of the [*Kalajdzic*] opinion as they relate to the parties' briefing," ECF No. 100. In *Kalajdzic*, the parties—as here—"acknowledged . . . that *Althen* prong one requires proof by a preponderance of the evidence," however, the petitioner "appear[ed] to . . . argu[e] that the requirements of the preponderance standard are more relaxed than what the law mandates." *Kalajdzic*, No. 23-1321, slip. op at 5 (Fed. Cir. June 20, 2024). The Federal Circuit first explained *Andreu*'s "biological plausibility" language could not "have endorsed a lower standard of proof than the preponderance standard" because "prong one was not disputed" in that case. *Id.* (citing *Andreu*, 569 F.3d at 1375). Thus, after stating without explanation neither *Kottenstette* nor *Capizzano* "undercut[] the requirement that a petitioner's medical theory must be proven by preponderant evidence," *id.*, the Federal Circuit concluded in *Kalajdzic* any standard for prong one "less than preponderance . . . is plainly inconsistent with [Federal Circuit] precedent." *Id.* The Court's decision here requiring preponderant evidence, *see supra*, to prove petitioner's theory under *Althen* prong one is consistent with *Kalajdzic*. To the extent *Kalajdzic* signaled a shift in Federal Circuit jurisprudence toward requiring preponderant evidence of a *persuasive* theory, however, the Court is unable to reconcile this with the Circuit's previous decisions in *Moberly*, *LaLonde*, and *Boatmon*, *see supra*. Neither can the Court reconcile this decision with *Kottenstette*, in which the Federal Circuit approved of "[t]he . . . special master's statement that 'medical probability means biological credibility[']" and stated, "biological credibility" "does not set a new lower . . . standard; it correctly recites [the Federal Circuit's statement in several precedential cases." *Kottenstette*, 861 Fed. Appx. a 440–41. *Kalajdzic* therefore further exemplifies the need for clarity related to *Althen* prong one, *see infra* n.7.

[5] *Paluck* and *Sharpe* discuss plausibility with respect to the last three prongs of the *Loving* test for off-table significant aggravation claims, *see Loving ex rel. Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135 (2009), which directly mirror the three-part *Althen* test. *See Sharpe*, 964 F.3d at 1083; *Paluck*, 786 F.3d at 1379–80.

by preponderant evidence each of the requirements set forth in *Althen*") (cleaned up)), but to the extent the Special Master required petitioner to "present a persuasive theory," the Special Master improperly elevated petitioner's burden under *Althen* prong one "not in accordance with [the] law." 42 U.S.C. § 300aa-12(e)(1)–(2); *see Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009); SM Dec. at 8. Indeed, at least since *Althen*, the Federal Circuit has recognized "requiring that the claimant provide proof of medical plausibility . . . is merely a recitation of this court's well-established precedent." *Althen*, 418 F.3d at 1281; *see* Tr. at 36:22–38:5 (petitioner explaining *Althen* "[a]t page 1281 . . . [said] there's nothing wrong with plausibility"). Were the Court to require "[p]etitioner[s] . . . [to] provide[] evidence that is both persuasive and reliable" to prove persuasive theories in off-table cases as proposed by both respondent and the Special Master, *see, e.g.*, Tr. at 24:2–12, it would be virtually impossible to make a "finding of causation in a field bereft of complete and direct proof."[6] *Althen*, 418 F.3d at 1280; *see* Tr. at 46:6–50:3 ("THE COURT: So in [*Andreu*,] . . . [the] Federal Circuit . . . cautions requiring epidemiological studies or general acceptance in the scientific or medical communities impermissibly raises a claimant's burden . . . . What I'm wondering is how is it that what the Government is articulating now for *Althen* prong one does not fall into that category that the Federal Circuit seems to be directly cautioning against here? . . . [RESPONDENT:] [Petitioners] are just required to provide convincing evidence to support that association between the vaccine and the injury. . . THE COURT: But that sounds like epidemiological studies or general acceptance in the scientific or medical communities, right? . . . What I'm asking is, is the standard Respondent is articulating here, how is it not in those categories which the Federal Circuit is cautioning against? . . . [I]t seems to me that this whole discussion here from the Circuit is talking about a plausible theory and anything that would require something that would automatically reject what just happens to be plausible, then, is something that Congress, according to the Circuit, cautioned against because close calls regarding causation are resolved in favor of injured claimants . . . [RESPONDENT:] This is true."). Although the Court agrees with respondent "science is evolving all the time," *see* Tr. at 27:24–29:21, advances in immunology cannot impact this Court's application of the Vaccine Act. This case accordingly must be remanded for the Special Master to consider whether petitioner presented preponderant evidence "causally connecting the vaccination and the injury," *Althen* F.3d at 1278, via a *biologically plausible theory*, namely molecular mimicry, *see* SM Dec. at 6. *Andreu*, 569 F.3d at 1375 (holding petitioners "met the first . . . prong[] of the *Althen* test" because their expert "presented a 'biologically plausible' theory" of general causation); *see* Tr. at 15:24–17:2. The Special Master therefore should not require petitioner present "a persuasive theory to explain how a flu vaccine could cause CIDP." SM Dec. at 13. Rather, the Special Master must determine whether petitioner has presented preponderant evidence linking the flu vaccine to CIDP via a biologically plausible theory.[7] *Andreu*, 569 F.3d at 1375; *Althen*, 418 F.3d at 1278 (requiring petitioners to

[6] To the extent the Special Master rejected petitioner's theory because petitioner did not present data that might otherwise be sufficient to associate the flu vaccine with CIDP on the Vaccine Injury Table, *see* SM Dec. at 20, the Court is wary of the impact of such a high burden on claimants' ability to recover "in a field bereft of complete and direct proof." *Althen*, 418 F.3d at 1280. Indeed, at oral argument, respondent admitted it is "not sure" what "the difference . . . in requirements [between off-table injuries and injuries placed on the table would be] if we[were to] look[] for preponderant evidence of a persuasive theory" for off-table cases. *See* Tr. at 27:6–16.

[7] The Court notes many of the Federal Circuit cases interpreting *Althen* use similar yet divergent language when discussing petitioner's burden under *Althen* prong one, *compare Althen*, 418 F.3d at 1278 (requiring petitioners "show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury . . ."), *with Oliver*, 900 F.3d at 1361 (requiring petitioners "show

prove by a preponderance of the evidence the existence of a medical theory "causally connecting the vaccination and the injury").

VII. CONCLUSION

For the foregoing reasons, the Court **VACATES** the Special Master's decision finding petitioner did not meet his burden to demonstrate by a preponderance of the evidence a causal connection between the flu vaccination and CIDP, ECF No. 89. The Court therefore **GRANTS** petitioner's Motion for Review, ECF No. 91, and **REMANDS** this case to the Special Master to determine whether petitioner can satisfy the *Althen* test as explained in this Opinion and Order.

IT IS SO ORDERED.

s/ Ryan T. Holte
RYAN T. HOLTE
Judge

by preponderant evidence *each of the requirements* set forth in *Althen*") (emphasis added) (internal quotations omitted); *compare also Andreu*, 569 F.3d at 1375 (accepting a biologically plausible theory under *Althen* prong one), *with Kottenstette*, 861 Fed. App'x. at 440–41 (accepting a biologically credible theory), *and Boatmon*, 941 F.3d at 1362 (requiring petitioners "show by a preponderance of the evidence" their proposed "theory . . . is a sound and reliable theory" of causation.). The goal of the Vaccine Act and Vaccine Rules of the United States Court of Federal Claims (VRCFC) "to decide . . . case[s] promptly and efficiently" would be best served by more clarity as to what is required under *Althen* prong one. *See* VRCFC 1(b).